DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Medical Device Quality Systems Inspection Technique; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshops.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Devices and Radiological Health, and the Regional Small Business Assistance Offices in cooperation with the American Society for Quality, Association of Food and Drug Officials, BioFlorida, Inc., Health Industry Manufacturers Association, Medical Alley, New England Biomedical Discussion Group, Organization of Regulatory and Clinical Associates, Pharmaceutical Quality Institute, and the Regulatory Affairs Professionals Society is announcing a series of workshops on the FDA Quality System Inspection Technique (QSIT). Topics for discussion include: Development of QSIT, Compliance Program and Warning Letter (Pilot), Management Controls, Corrective and Preventative Action, Design Controls, Production and Process Controls, and Industry Perspective of QSIT. Through the workshops, FDA seeks to increase the medical device community's understanding of QSIT, and ensure that the device industry takes appropriate actions to establish effective quality systems, thus preventing regulatory problems when inspections occur.

Date and Time: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

Location: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

Registration: Send registration information as listed in the **SUPPLEMENTARY INFORMATION** section of this document, along with the correct payment amount, to the registrar for the site you wish to attend. Fees cover refreshments, organization and site costs, and materials. Space is limited,

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therefore interested parties are encouraged to register early. If you need special accommodations due to a disability, please inform the registrar for your site at least 7 days in advance of the workshop.

Contact: Herman B. Janiger, Northeast Regional Office (HFRNE–17), Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 718–340–7000, ext. 5528.

SUPPLEMENTARY INFORMATION: In the fall of 1999, FDA field offices will begin using the QSIT nationwide as the primary tool for medical device good manufacturing practice/quality system inspections. QSIT was developed using a collaborative effort with stakeholders and tested in three districts. The following workshops are scheduled to increase the medical community's understanding of QSIT:

TABLE 1.

Workshop Address	Date and Local Time	Deadline to Register and Fee	Registrar and Cosponsor	FDA Contact Person
EAST ELMHURST: Crowne Plaza, LaGuardia Airport, 104–04 Ditmars Blvd., East Elmhurst, NY 11369, 718–457–6300.	Tuesday, October 12, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, September 28, 1999, $170.	James Blanchard, Health Industry Manufacturers Association, 1200 G St. NW, suite 400, Washington, DC 20005, 202–434–7231, FAX 202–783–8750.	Herman B. Janiger, Small Business Representative, Northeast Regional Office, 718–340–7000, ext. 5528.
PRINCETON: Holiday Inn, US Route 1 & Ridge Rd., Princeton, NJ 08540, 609–452–2400 or 800–465–4329.	Thursday, October 14, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, September 30, 1999, $145.	Satish Laroia, Pharmaceutical Quality Institute, 33 Aspen Circle, Edison, NJ 08820, 973–890–1440, FAX 732–549–7487.	Marie T. Falcone, Small Business Representative, Central Regional Office, 215–597–2120, ext. 4003.
MINNEAPOLIS: Holiday Inn, Minneapolis West, 9970 Wayzata Blvd., Minneapolis, MN 55426, 612–593–1918 or 800–465–4329.	Thursday, October 21, 1999, 8:30 a.m. to 4:30 p.m.	Friday, October 15, 1999, $160 (member), $235 (nonmember).	Lisa Miller, Medical Alley, 1550 Utica Ave. South St., Louis Park, MN 612–542–3077, FAX 612–542–3088, or "www.medicalalley.org".	Marie T. Falcone, Small Business Representative, Central Regional Office, 215–597–2120, ext. 4003.
ORLANDO: Radisson Orlando Airport, 5555 Hazeltine National Dr., Orlando, FL 32812, 407–856–0100 or 800–333–3333.	Thursday, October 28, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, October 14, 1999, $90.	Larry M. Clark, BioFlorida, Inc., 15205 SW 78th CT, Miami, FL 33157, 305–971–1495, FAX 305–971–1496.	Barbara Ward-Groves, Small Business Representative, Southeast Regional Office, 404–253–2238.
CAMBRIDGE: Volpe National Transportation Systems, Center Auditorium, rm. 1–11, Bldg. 2, Kendall Sq., Cambridge, MA 02142–1093.	Tuesday, November 2, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, October 19, 1999, $50.	Terrence Sullivan, New England Biomedical Discussion Group, P.O. Box 1282, Attleboro Falls, MA 02763–0282, 508–643–0434, FAX 508–643–2237.	Herman B. Janiger, Small Business Representative, Northeast Regional Office, 718–340–7000, ext. 5528.
HOUSTON: Marriott West Loop, 1750 West Loop South, Houston, TX 77027, 713–960–0111 or 800–228–9290.	Thursday, November 4, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, October 21, 1999, $170.	Denise Rooney, Association of Food and Drug Officials, P.O. Box 3425, York, PA 17402, 717–757–2888, FAX 717–755–8089.	Brenda C. Baumert, Small Business Representative, Southwest Regional Office, 214–655–8100, ext. 133.

TABLE 1.

Workshop Address	Date and Local Time	Deadline to Register and Fee	Registrar and Cosponsor	FDA Contact Person
OAK BROOK: Marriott Oak Brook, 1401 West 22d St., Oak Brook, IL 60523, 630–573–8555 or 800–228–9290.	Wednesday, November 10, 1999, 8:30 a.m. to 4:30 p.m.	Wednesday, October 27, 1999, $80.	Susan B. Jacobs, American Society for Quality, 3516 North Wilshire Dr., Palatine, IL 60067, 847–359–4456, FAX 847–359–4512.	Marie T. Falcone, Small Business Representative, Central Regional Office, 215–597–2120, ext. 4003.
ATLANTA: Sheraton Colony Sq., 188 14th St. NE., Atlanta, GA 30361, 404–892–6000.	Tuesday, November 16, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, November 2, 1999, $170.	Denise Rooney, Association of Food and Drug Officials, P.O. Box 3425, York, PA 17402, 717–757–2888, FAX 717–755–8089.	Barbara Ward-Groves, Small Business Representative, Southeast Regional Office, 404–253–2238.
FOSTER CITY: Crowne Plaza Hotel, 1221 Chess Dr., Foster City, CA 94404, 650–570–5700.	Thursday, November 18, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, November 4, 1999, $120.	Courtney Ford, Regulatory Affairs Professionals Society, 12300 Twinbrook Pkwy., suite 350, Rockville, MD 20852–1606, 301–770–2920, FAX 301–770–2924.	Acting Small Business Representative, Pacific Regional Office, 510–637–3980.
BELLEVUE: Rockwell Institute, 13218 North East 20th St., Bellevue, WA 90005, 425–747–7272.	Tuesday, November 23, 1999, 8:30 a.m. to 4:30 p.m.	Sunday, November 7, 1999, $100.	Jaimee Hansen, Organization of Regulatory & Clinical Associates, P.O. Box 3490, Redmond, WA 98073–3490, 425–487–7179, FAX 425–487–8666.	Acting Small Business Representative, Pacific Regional Office, 510–637–3980.

The workshops, scheduled above, will help to implement the FDA Plan for Statutory Compliance (developed under section 406 of the FDA Modernization Act (21 U.S.C. 393)) through working more closely with stakeholders and ensuring access to needed scientific and technical expertise. These workshops also comply with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) that requires outreach activities by Government agencies directed to small businesses.

This notice announcing the workshops and a registration form may also be accessed at the CDRH website at ''http://www.fda.gov/cdrh/fedregin.html''.

The following information is requested for registration:

[Insert Form Here]

REGISTRATION FORM

Quality System Inspection Technique (QSIT)

Regional Medical Device Workshop

Instructions: To register, complete this form and mail with registration fee to the Registrar for the workshop you wish to attend.

Date, _____

Location, _____

Fee enclosed, _____

Name, _____

Title, _____

Company, _____

Address, _____

Telephone, _____

Fax, _____

E-mail _____

7. Address,

8. Telephone,

9. Fax, and

10. E-mail.

Dated: 9/2/99

September 2, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

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